

Generic Questionnaire for the Production of Peptides

Principal Investigator:

Institution/Affiliation:

1. Amount(s) of delivered product(s) desired
 - a. Non-GMP (laboratory grade)
 - b. GMP (clinical grade)
2. Peptide Information
 - a. Sequence/reference to sequence
 - b. Any unusual amino acids or properties of the peptide
3. Are there issues of solubility and formulation that must be resolved?
4. What is the largest amount of material produced in your laboratory in a single production batch?
5. Do you have material to supply as reference standard? Please provide details of analysis for identity, purity, and potency.
6. Do you have material to supply as bulk drug for preliminary pharmacology and toxicology studies? Please indicate how much is available and provide details of analysis for identity, purity, and potency.
7. Are there concerns about physical properties such as folding, dimerization, stability, or other important properties?
8. Have you established reproducible assays for identity, purity, potency for your product? Please provide details.
9. Please describe your proposed list of release criteria
10. In what form (lyophilized powder, formulated product, etc.), fill size and concentration do you want for the final product? Have you evaluated any formulations for your peptide?
11. Have you investigated possible sources of production with other commercial firms? If so, provide details.
12. Have you developed any information regarding estimated costs?
13. Are there safety issues connected with production, purification, and/or handling?
14. Please describe the status of product(s) regarding intellectual property issues
15. If the proposed project(s) is an improvement or modification of an existing approach,

provide brief summary of nature of any such antecedents or other approaches that may appear closely related (information provided may affect analysis of feasibility, cost, production issues, may be important in consideration of intellectual property issues).

16. Have you had or are you preparing to have any meeting with regulatory agencies, such as a pre-IND meeting with the USFDA? If yes, please indicate the type of meeting, the regulatory agency, and the date or proposed date.
17. Who will sponsor the IND for the clinical study?